



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2015-0373; FRL-9941-17]

**Propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol;**

**Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol when used as an inert ingredient (solvent, co-solvent) in pesticide formulations applied to growing crops or raw agricultural commodities under the EPA's regulations. Dow AgroSciences submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

**SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0373, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW. Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0373 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information

not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0373, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of August 26, 2015 (80 FR 51759) (FRL-9931-74), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10786) by Dow AgroSciences, 9330 Zionville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol (CAS Reg. No. 25265-

77-4) when used as an inert ingredient as a solvent or co-solvent in pesticide formulations applied to growing crops or raw agricultural commodities after harvest. That document referenced a summary of the petition prepared by Dow AgroSciences, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

### **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated

dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol including exposure resulting

from the exemption established by this action. EPA's assessment of exposures and risks associated with propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol has low acute toxicity with oral lethal dose (LD)<sub>50</sub> values >3,200 milligram/kilogram (mg/kg), dermal LD<sub>50</sub> values >14,000 mg/kg, and inhalation lethal concentration (LC)<sub>50</sub> values > 3.55 mg/liter (L) in rats, rabbits, and guinea pigs. In a 15-day oral gavage study in rats, the NOAEL was >1,000 mg/kg /day. In a combined repeat dose toxicity and developmental and reproductive toxicity screening test in rats, no reproductive or developmental toxicity was observed at doses up to 1,000 mg/kg body weight (bw)/day, the highest dose tested.

No chronic toxicity studies were available; however, the lack of systemic toxicity in two shorter repeat dose studies at the limit dose of 1,000 mg/kg bw/day indicates that chronic toxicity is not a concern.

Propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol was negative genotoxicity in the Ames assay and in vivo micronucleus assay.

No cancer study is available for propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol, however based on the lack of genotoxicity, no adverse effects seen in subchronic toxicity studies, and structure–activity relationship models (QSAR) modeling that did not indicate any triggers for carcinogenicity, propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol is not expected to be carcinogenic.

Propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol is a mixture of the 1-substituted (-65%) and the 3-substituted (-35%) monoisobutyrate isomers of 2,2,4-trimethyl-1,3-pentanediol. The half-life of the 1-substituted isomer in human and rat blood is between 15 to 22 minutes. No specific information is available on toxicity of propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol metabolites. However, propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol is rapidly metabolized in rat blood, and toxicity of parent propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol in rats was not observed at doses up to 1,000 mg/kg /day, so metabolite toxicity is anticipated to be low.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk



posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

*<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.*

Since there is no indication of toxicity at the limit dose, a toxicological endpoint of concern for risk assessment purposes was not identified. Since no endpoint of concern was identified for the acute and chronic dietary exposure assessment and short and intermediate dermal and inhalation exposure, a quantitative risk assessment for propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol is not necessary.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol, EPA

considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol in food as follows:

Dietary exposure can occur from eating foods containing residues of propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol. Because no hazard endpoint of concern was identified for the acute and chronic dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

2. *Dietary exposure from drinking water.* Propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol residues may be found in drinking water. However, since an endpoint of concern was not identified for the dietary assessment (food and drinking water), a quantitative dietary exposure risk assessment was not conducted.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol is used as an inert ingredient in pesticide products that could result in short- and intermediate-term residential exposure. However, based on the lack of toxicity, a quantitative exposure assessment from residential exposures was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning

the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol to share a common mechanism of toxicity with any other substances, and propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

Based on an assessment of propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children, and has determined that a qualitative assessment is appropriate. As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD

(cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

Based on the lack of any toxicological endpoints of concern, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol residues.

## **V. Analytical Enforcement Methodology**

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

## **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol (CAS Reg. No. 25265-77-4) when used as an inert ingredient (solvent or co-solvent) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest.

## **VII. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of

Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or

between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 12, 2016.

Susan Lewis,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, add alphabetically the entry “Propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol” to the table to read as follows:

**§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * *	* *	* *
Propanoic acid, 2-methyl-, monoester with 2,2,4-trimethyl-1,3-pentanediol (CAS Reg. No. 25265-77-4)		Solvent, co-solvent
* * *	* *	* *

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